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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

JOYNER, KEVIN

ART UNIT	PAPER NUMBER
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1744

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/531,297	MOLLER ET AL.	
	Examiner	Art Unit	
	Kevin C. Joyner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 20-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/1/05, 4/14/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I Group I, claim(s) 1-19, drawn to a device for sterilization.
- II Group II, claim(s) 20-35, drawn to a method of sterilizing packages.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

3. As stated under PCT Rule 13, a group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical feature is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. The single general inventive concept and special technical feature in the instant application comprises sterilizing packages with an open end and a closed end with a gaseous agent wherein the ambient temperature and concentration of

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sterilizing agent in the sterilization zone is measured and used for controlling the amount of sterilizing agent introduced in the sterilization zone. This concept is taught by Zelina in U.S. Publication No. 2002/0159915. Therefore, the single inventive concept cannot be considered a special technical feature because it does not make a contribution over the prior art. Consequently, the inventions listed as Groups I and II do not relate to a single general inventive concept.

4. During a telephone conversation with Mr. Mathew Schneider on March 1, 2007 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-19. Affirmation of this election must be made by applicant in replying to this Office action. Claims 20-35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 9 recites the limitation "before filling of the packages" in line 2. There is insufficient antecedent basis for this limitation in the claim. More specifically, there is no reference in the claim from which it depends to the limitation of filling of the packages. Corrective action is required.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 3-6, 8-14 and 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Zelina et al. (U.S. Publication No. 2002/0129915).

Zelina discloses a device for sterilization in production of packages which is adapted for sterilization with a gaseous sterilizing agent kept in the gaseous phase throughout the sterilization process, said device comprising a heating zone (170) a sterilization zone (11) and a venting zone (182) as shown in Figure 8, an ambient temperature sensor (152) that is capable of sensing the ambient temperature outside the device as shown in Figure 1, a concentration meter (153) that is capable of measuring the concentration of sterilizing agent in the sterilization zone as shown in

Figure 8, and a first control unit (150) for controlling the amount of sterilizing agent introduced in the sterilization zone based on the temperature measured by the ambient temperature sensor and the concentration measured by the concentration meter as disclosed in paragraph 57.

In regards to claim 3, Zelina continues to disclose that the device further comprises a package heating temperature sensor that is capable of sensing the temperature of the packages before entry into the sterilization zone as disclosed in paragraph 59. More specifically, the paragraph discloses that in an alternate embodiment the temperature of the individual containers are measured if the process cannot control the temperature of the incoming containers accurately. Therefore, the sensor of the alternate embodiment provides a sensor that is fully capable of measuring the temperature of the packages before entry into the sterilization zone.

Concerning claim 4, the device further comprises a feedback circuit that is capable of controlling the heating in the heating zone based on the temperature of the packages as disclosed in paragraphs 57 and 58.

Regarding claim 5, the reference continues to disclose that the device comprises a condensation detector that is capable of detecting condensation in the sterilization zone as disclosed in paragraph 59. Concerning claim 8, the reference also teaches that the gaseous sterilizing agent is hydrogen peroxide in paragraph 14. In regards to claim 10, the reference teaches that the device sterilizes the packages before filling the packages with said packages having an open end and a closed end as shown in Figure 8.

Concerning claim 6, the device further comprises a means for maintaining a higher pressure in the sterilization zone than in the heating zone and venting zone. More specifically, the venting zone has a vacuum pump that creates a negative pressure in that zone, thus creating a means for maintaining a higher pressure in the sterilization zone than in the venting zone. The sterilization zone has fill lines (172) that supply vapor to the sterilization zone causing a positive pressure in that zone. Since there is no source of positive pressure in the heating zone as shown in Figure 8, then the sterilization zone comprises a means for maintaining a higher pressure in the sterilization zone than in the heating zone.

Regarding claim 10, Zelina continues to disclose that the heating zone comprises means (171) that is capable of heating the packages to a temperature above a dew point of the sterilizing agent used in the sterilization zone as disclosed in paragraph 62.

Concerning claim 11, the reference also discloses that the venting zone comprises means that is capable of venting away the sterilizing agent used in the sterilization zone from the packages after sterilization as disclosed in paragraphs 64 and 65.

Concerning claims 12 and 13, the reference continues to disclose that the device comprises means for controlling a flow of gaseous sterilizing agent in the sterilization zone, such that the gaseous sterilizing agent flows essentially in a direction from the open end of the packages toward the closed end of the packages as well as introducing the gaseous sterilizing agent in a top portion of the sterilization zone and evacuating the

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sterilizing agent in a bottom portion of the sterilization zone, and maintaining a flow of gaseous sterilizing agent essentially from top to bottom as disclosed in paragraph 63.

In regards to claim 14, the reference also teaches that the device comprises a means for controlling the venting air flow in the venting zone such that the venting air flows essentially in a direction from the open end of the packages toward the closed end of the packages as shown in Figure 8 and disclosed in column 65. Concerning claim 16, the reference teaches that the device is fully capable of sterilizing itself internally. More specifically, the hydrogen peroxide and the heaters in the sterilization and heating zones will not only sterilize the bottles themselves but also the area around the bottles and the structural parts inside zones. Regarding claims 17 and 18, the reference teaches that the device comprises means (171) for heating the interior of the device and a unit (10) for production of the gaseous sterilizing agent as shown in Figure 8. Regarding claim 19, Zelina continues to disclose that the device comprises a filling zone (190) for filling packages and means for maintaining a higher pressure in the filling zone than in the venting zone. More specifically, the filling zone (190) operates under an ambient pressure and the venting zone (182) operates under a negative pressure from the exhaust line (182) and the vacuum pump (184). Thus, the exhaust line and the vacuum pump is a means for maintaining a higher pressure in the filling zone than in the venting zone.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 2, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zelina (U.S. Publication No. 2002/0159915) in view of Taggart (U.S. Publication No. 2001/0000558).

In regards to claim 2, Zelina is relied upon as set forth above. Zelina does not specifically state that the device comprises a package start temperature sensor for sensing the temperature of the packages entering the heating zone. Taggart discloses a device for sterilization in the production of packages with a sterilizing agent, said device comprising a sterilization zone (zones 60 and 116) and a heating zone (152). The reference continues to disclose that apparatus comprises a temperature start sensor (H) that is capable of sensing the temperature of the packages entering the heating zone as shown in Figure 16. More specifically, two temperature sensors are located in the heating zone (152). Each sensor is located at one end of the zone as shown in Figure 16. The packages move through the apparatus from left to right in Figure 16 (paragraphs 46 and 47). The sensor on the left side is fully capable of sensing the temperature of the packages entering the heating zone because of its position in the zone. Therefore, it would have been obvious to one of ordinary skill in

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the art at the time of the invention to modify the apparatus of Zelina to include a temperature sensor for sensing the temperature of the packages entering the heating zone to control the process as efficiently and effectively as possible as exemplified by Taggart.

Concerning claim 7, Zelina is relied upon as set forth above, wherein the reference continues to disclose that the device contains HEPA filters in between each zone to deter any cross contamination as disclosed in paragraph 65. However, Zelina does not specifically disclose that the partitionings (referenced as HEPA filters) have openings for the passage of the packages. Taggart discloses a device for sterilization in the production of packages with a sterilizing agent, said device comprising a sterilization zone (zones 60 and 116) and a heating zone (152). The reference further discloses that the zones are separated from each other by means of partitionings having openings for the passage of packages to control the flow of sterile air throughout the apparatus (paragraphs 64-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Zelina to include partitionings having openings between each zone to permit the passage of packages and control the flow of sterile air as exemplified by Taggart.

13. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zelina (U.S. Publication No. 2002/0159915) in view of Niwa (U.S. Publication No. 2001/0000558).

Concerning claim 15, Zelina is relied upon as set forth above, wherein the reference further discloses a means (186 and 188) for controlling the flow of venting air

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arranged to introduce the venting air in a top portion of the venting zone, and maintaining a flow of venting air essentially from top to bottom as shown in Figure 8. Zelina does not appear to disclose that the air is evacuated in the bottom portion of the venting zone. Niwa discloses a device used in the production of packages that includes a sterilization zone as well as a venting zone (referenced as a dearation of filling of inert gas) as shown in Figure 1. The reference further discloses that the device comprises a means for controlling a venting air flow in the venting zone, wherein the means for controlling the flow of venting air are arranged to introduce the venting air in a top portion of the venting zone and to evacuate the venting air in a bottom portion of the venting zone, maintaining a flow of venting air essentially from top to bottom (column 9, lines 7-45. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Zelina to evacuate the air in the bottom portion of the venting zone in order to utilize the effects of gravity and efficiently remove any unnecessary components away from the sterilized packages.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Joyner whose telephone number is (571) 272-2709. The examiner can normally be reached on M-F 8:00-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCJ


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